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Evaluating the efficacy of the Thai Health Improvement Profile intervention for preventing weight gain in people with early stage psychosis: A randomized controlled trial

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ABSTRACT

Objectives: To investigate the efficacy of the Thai Health Improvement Profile intervention for preventing clinically significant weight gain in people with early stage psychosis.
Methods: We undertook a randomised controlled trial from 10/2018 to 05/2021. Participants with early stage psychosis (<5 year duration) were recruited using convenience sampling from the caseloads of community psychiatric nurses in Thailand and randomly allocated to either the Thai Health Improvement Profile intervention or treatment as usual group following baseline assessment. Outcome assessors were blind to group allocation, whereas participants were not. Participants in the intervention group received three monthly (five in total) systematic health checks using the Thai Health Improvement Profile tool, which was used to develop a personal health plan in collaboration with a family member/carer. Nurses supported participants to implement the health plan using behaviour change techniques derived from motivational interviewing. The treatment as usual group consisted of medication and psychosocial support, and no additional intervention was provided. The primary outcome was weight gain (defined as a greater or equal to 7 % increase in weight against baseline) within 1 year.
Results: Fifty-three participants were allocated to the intervention and an equal number to the treatment as usual group. Primary outcome data were available for 30 participants in each group at the 12 month follow-up. We undertook an intention to treat analysis with multiple imputation (to handle the missing data) for the primary outcome. The treatment as usual group was found to have higher odds than the Thai Health Improvement Profile intervention group of gaining ≥7 % of baseline body weight (OR = 6.52; 95 % CI: 1.88–22.65, p = 0.004).
Conclusions: The Thai Health Improvement Profile intervention was effective at preventing weight gain in people with early stage psychosis at one year, though attrition was relatively high. The results highlight the need for community mental health nurses to adopt a holistic approach, the potential benefits of conducting regular comprehensive health checks and the importance of involving family members when aiming to improve the physical health of people diagnosed with early stage psychosis. A large definitive multi-site randomised controlled trial of the Thai Health Improvement Profile with a longer follow-up is now justified.
Trial registration: Prospectively registered with the Thai Clinical Trials Registry (reference: TCTR20180305002).

What is already known

- People with psychosis have worse physical health and substantially shorted life expectancy than the general population.
- Clinically significant weight gain is common in people with early psychosis and directly contributes to excess mortality.

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- There is no robust evidence base for effective interventions to prevent weight gain in people experiencing early stage psychosis.

What this paper adds

- The Thai Health Improvement Profile intervention was safe and effective at preventing clinically significant weight gain in people with early psychosis over one year compared to usual care.
- The integration of the Thai Health Improvement Profile as part of standard of care for people with early psychosis should be further examined.
- A large definitive randomised controlled trial of the Thai Health Improvement Profile is now justified and future multi-site studies with a longer (24–36 months) follow-up should also be considered.

1. Introduction

Compared with the general population, people with psychosis (schizophrenia spectrum disorders and bipolar disorder) have worse physical health and substantially shorter life expectancy, primarily due to increased rates of cardiovascular disease (DeHert et al., 2011). A systematic review and meta-analysis of 11 observational studies involving 247,603 participants reported 14.5 years of potential life lost in people with schizophrenia compared to healthy controls (Hjorthøj et al., 2017). A constellation of risk factors contributes to lower life expectancy including obesity, poor diet, lack of exercise/sedentary lifestyle, smoking, and medication side effects (Vancampfort et al., 2019).

Weight gain is an important modifiable health risk factor for people experiencing early stage psychosis as it increases the risk of diabetes and cardiovascular disease, as well as impacting quality of life (DeHert et al., 2011). Weight gain predominantly occurs in the first few months of treatment in people with early stage psychosis (Manu et al., 2015), and is often associated with the use of psychotropic medication. For example, a systematic review and meta-analysis by De Hert et al. (2012) reported average weight gain of 3.8 kg in the first three months of starting treatment with antipsychotic medication.

Treatment with antipsychotic medication (particularly olanzapine), which is standard care for people with early stage psychosis, is often considered to be the cause of weight gain (Manu et al., 2015), but lifestyle factors also play an important role. For example, a systematic review and meta-analysis that included 69 observational studies involving 35,682 participants found that people with severe mental illness were much more sedentary during waking hours and less physically active compared with age and gender matched controls (Vancampfort et al., 2017). A population study involving 68,879 participants demonstrated that people with severe mental illness consumed both more calories and obesogenic nutrients than age and gender matched controls (Firth et al., 2018).

An umbrella review of 27 meta-analyses (128 discrete trials, involving 47,231 participants) regarding pharmacological and non-pharmacological interventions to improve physical health in schizophrenia found that a range of interventions reduced body weight with a large effect size, including lifestyle counselling, exercise interventions, and psychoeducation (respective standardised mean differences −0.98, −0.96, −0.77) (Vancampfort et al., 2019). The methodological quality of primary trials included in the reviews was consistently rated as having a high risk of bias, the authors concluding that further large methodologically rigorous trials were justified (Vancampfort et al., 2019). The Vancampfort et al. (2019) study did not include any reviews with a specific focus on people with early stage psychosis.

A recent scoping review of lifestyle interventions to improve the physical health of people with early psychosis (Hui et al., 2021) included 22 reports of which three were randomised clinical trials testing novel interventions (Fisher et al., 2020; Holt et al., 2018; Lovell et al., 2014). Fisher et al. (2020) randomly allocated 22 men with early psychosis to receive a 12-week exercise training programme or treatment as usual. The results demonstrated that it was feasible to engage people with early psychosis in an exercise training intervention; 83 % of participants attended the exercise sessions twice per week, and 41 % attended three times per week. Holt et al. (2018) conducted a randomised controlled trial (RCT) of a lifestyle self-management intervention (plus support and booster sessions) with 414 early psychosis patients. The results showed that there was no statistically significant difference between the groups in weight at 12-months (Holt et al., 2018). A healthy living intervention tested in a trial involving 105 people attending early intervention services in England showed no change in Body Mass Index (BMI), the primary outcome, at 12 months (Lovell et al., 2014). We identified one further trial (Alvarez-Jimenez et al., 2006) that was not included in the Hui et al. (2021) scoping review. Sixty-one people with early psychosis were randomly allocated to an early behavioural intervention or non-structured physical care; respectively, 40 % and 79 % had a clinically significant increase in weight (defined as a greater that 7 % increase in body weight) (Alvarez-Jimenez et al., 2006).

Given the earlier equivocal findings and the small number of trials focused on preventing clinically significant weight gain in people experiencing early stage psychosis there is a strong scientific justification for an adequately powered, methodologically rigorous clinical trial of a novel intervention in this patient group. The Health Improvement Profile (Hardy et al., 2015) is a potential candidate intervention for weight management in people with early stage psychosis. The Health Improvement Profile intervention consists of a gender-specific manualised and systematic health check that is utilised by clinical staff to identify objective physical health related risks and unhealthy lifestyle behaviours that are flagged as green (no risk) or red (risk). The Health Improvement Profile also provides directions for appropriate interventions for each area with a red flag. The Health Improvement Profile results are then used by clinical staff to collaboratively construct a care plan to address areas of risk with the patient. Previous studies have demonstrated the clinical utility of modified versions of the Health Improvement Profile in a variety of international settings, including Finland (Werkkala et al., 2020), UK (Shuel et al., 2010), Hong Kong (Bressington et al., 2014, 2018) and Australia (Jones et al., 2016). An earlier pilot study of the Health Improvement Profile in Thailand (Meepring et al., 2018) showed that incorporating motivational interviewing principles resulted in statistically significant reductions in the bodyweight (−1.13 kg, $p < 0.001$) and mean BMI (−0.78 kg/m^2, $p < 0.001$) in people with psychosis when they attended clinical meetings with a family member. Therefore, in this trial we proposed pragmatically combining the Health Improvement Profile intervention with family-inclusive motivational interviewing-based lifestyle/behaviour change counselling as a weight management intervention for people with early stage psychosis (Rubak et al., 2005).

1.1. Study aim

This outcome assessor-blinded randomised controlled trial aimed to investigate the efficacy of the Thai Health Improvement Profile intervention in preventing weight gain, reducing indicators of obesity and improving the health-related quality of life of people diagnosed with early-stage psychosis when compared to treatment as usual (at 12 month follow-up).

The primary outcome of this trial was the prevention of ≥7 % weight gain over the 12-month duration of the intervention. Secondary outcomes were obesity (BMI and waist circumference measurement), health related quality of life and satisfaction with physical health care.

1.2. Hypotheses

When compared to treatment as usual, the Thai Health Improvement Profile intervention group will have significantly:

1. lower proportion of participants with ≥7 % body weight gain at 3 and 12 months after the start of the intervention;

2. greater reductions in participants' waist circumference/BMI at 3 and 12 months after the start of the intervention;
3. greater improvements in participants' self-reported health related quality of life at 3 and 12 months after the start of the intervention;
4. greater participant satisfaction with physical healthcare from baseline to 12 months after the start of the intervention.

2. Methods

2.1. Study design and protocol adherence

This study is a repeated measures assessor-blind randomised controlled trial. We previously completed an uncontrolled pilot study of the Thai Health Improvement Profile intervention delivered by community nurses to 105 patients with psychosis who were assessed at the baseline and twelve-month follow-up (Meepring et al., 2018). The pilot study confirmed that the combined intervention was acceptable to nurses and patients and was a promising intervention to manage body weight as 23 patients were found to have moved to a healthier BMI classification after one-year.

The trial protocol for this study was prospectively registered on 05/03/2018 with the Thai Clinical Trials Registry (reference: TCTR20180305002). There were two deviations from the registered protocol. The first was that we abandoned collecting data for one secondary outcome (cardiovascular disease risk as measured by the QRISK3 calculator) before all baseline data were collected. This was due to a lack of routinely collected blood test results available in the patient records (required for risk calculation) and 19 % (n = 21) of participants were aged under 25 years, whereas the QRISK3 calculator requires a minimum age of 25 years. The second deviation was that we did not analyse the within-intervention group differences in the total number of red flagged (at risk) individual items of the Thai Health Improvement Profile screening tool due to substantial amounts of missing data relating to blood test results at all time points. The original protocol also specified that prevention of weight gain and reduction of obesity indicators were both primary outcomes. For clarity, we have reported the prevention of weight gain as the primary outcome and the reduction of obesity indicators as a secondary outcome.

2.2. Study setting

The study was conducted in the outpatient clinic at a large public psychiatric hospital in semi-rural Northern Thailand with a catchment area consisting of a population of around 3 million people. Approximately 200 clients attend the multidisciplinary service daily.

2.3. Data collection

The demographic and outcome data were collected by an outpatient clinic nurse (who was blind to intervention/group assignment of participants). The primary outcome (weight) and two secondary outcomes (BMI and waist circumference) were extracted from the routine three-monthly metabolic screening data recorded in the patients' medical notes where available or were measured by the outpatient clinic nurse where missing or more than one month old. Patients' self- reported outcome measures and diet/exercise data were recorded at baseline and 3 months and 12 months after starting the intervention. Baseline data collection was conducted between 10/2018 and 04/2020 and the one-year follow-ups were conducted between 10/2019 and 05/2021.

2.4. Participant inclusion criteria

Patients were included if they met the following inclusion criteria:

- Diagnosed with any severe mental illness with psychotic symptoms within the past 5 years at time of recruitment (including, but not limited to, schizophrenia-spectrum disorders and affective disorders with psychotic features).
- Have been receiving any antipsychotic medication — either alone or in combination with other psychotropic medications.
- Adult Thai residents (at least 18 years old) receiving treatment/care at the designated out-patient clinic.
- Able to understand Thai, provide written informed consent, and considered competent to participate in the study, as confirmed by their treating psychiatrist.

Patients were excluded if they:

- Had co-morbidity of another chronic physical and/or mental health problem such as a learning disability, substance misuse disorders, or organic brain diseases.
- Planned or expected to stop taking their antipsychotic medication at recruitment (or before the use of Thai Health Improvement Profile).
- Were receiving any other physical health monitoring or intervention programme beyond usual care.

The rationale for including participants with less than 5 years of psychosis was based on recommendations that an operational definition of early stage psychosis should adopt a liberal cut-off point of up to 5 years because this is a period when patients may be more receptive to psychosocial interventions and their clinical needs remain relatively constant during the first five years after symptom onset (Breitborde et al., 2009; Carney et al., 2016). An earlier Thai Health Improvement Profile quasi-experimental study also demonstrated that improved bodyweight was associated with a shorter duration of psychosis (Bressington et al., 2018; Meepring et al., 2018).

2.5. Ethical considerations

Ethical approval to conduct this research was obtained from Nakhon Sawan Rajanagarindra Psychiatric Hospital (reference number 07/2560) prior to the commencement of the study. Potential participants' capacity to provide informed consent and safety to take part in the study were assessed by the treating clinical team. Written and verbal information about the study was provided to potential participants and they were encouraged to discuss the invitation with family members and the research team. In order to minimise perceived coercion to take part the recruitment was conducted by a research nurse who had no role in providing their ongoing treatment. Participants were made aware that declining the invitation or withdrawing from the study at any point would result in no negative impacts on their usual treatment or relationship with clinicians.

2.6. Sample size

At the time of designing this study (2017), there were no similar studies conducted with patients in Asian countries which used prevention of weight gain as a primary outcome, nor any relevant meta-analysis. Therefore, our sample size calculation was based on the effect sizes of psychosocial weight-gain prevention interventions for first episode psychosis conducted in Western countries by Curtis et al. (2016) and Alvarez-Jimenez et al. (2008). Both studies measured the clinical efficacy of health-counselling behavioural interventions in terms of preventing clinically significant weight gain (≥7 % of baseline weight) at three months after intervention. Curtis et al. (2016) reported that 75 % of patients in the usual care group gained clinically significant weight compared to 13 % in the intervention group. Whilst in the Alvarez-Jimenez et al. (2008) study 79 % of usual care patients gained >7 % of baseline weight compared to 39 % of patients in the intervention group. Cautiously assuming that 60 % of patients in the treatment-as-usual group versus 30 % in the Thai Health Improvement Profile group would experience ≥7 % gain of baseline weight, with a study power of

0.80 and a significance level of 0.05, 42 patients would be required in each group. Given that our previous Health Improvement Profile studies (Bressington et al., 2014; Meepring et al., 2018) demonstrated an attrition rate between 0 and 29 % over one year, we calculated we required a total of 108 patients (54 in each group).

2.7. Recruitment, randomisation and blinding

Outpatient medical records were screened to identify potential participants. Participants who met the study eligibility criteria were recruited using convenience sampling, where they were invited to take part on a consecutive basis of outpatient appointment attendance by a trained research nurse. Baseline measurements were completed after written informed consent was obtained. The allocation sequence was generated by randomiser.org using block randomisation (with random permuted block sizes) to balance group numbers and was retained by the trial coordinator (who had no role in participant recruitment). Following the baseline assessment, the research nurse contacted the trial coordinator to establish if each participant was assigned to either the Thai Health Improvement Profile treatment or treatment as usual group. The research nurse then informed the assigned community psychiatric nurses of the patients' treatment allocation who started the Thai Health Improvement Profile intervention or only treatment-as-usual for their patients. The group allocation was known by the trial coordinator (SM, who had no role in the recruitment, outcome assessment or data analysis), but the outpatient clinic staff conducting the primary outcome assessment (weight) and also the indicators of obesity (BMI and waist circumference — a secondary outcome) were blind to group allocation. Given the nature of the intervention and lack of an active control intervention, the community psychiatric nurses delivering the Thai Health Improvement Profile or treatment-as-usual and the patient participants were aware of group allocation throughout the study, therefore it was not feasible to blind them.

2.8. Thai Health Improvement Profile intervention

The interventions were carried out face-to-face with patient participants and their accompanying family member/carer by one of five trained community psychiatric nurses in the psychiatric outpatient department. The Thai Health Improvement Profile tool was used to facilitate an assessment of patients' physical health risks and actual problems, and related unhealthy lifestyle behaviours. The gender specific Thai Health Improvement Profile consists of 27 areas of physical health assessment for men and 28 areas for women (including BMI, waist circumference, blood pressure, pulse, cholesterol levels, dietary habits, exercise levels, fluid intake, alcohol use, substance misuse, self-checking behaviours, smoking status, regularity of health professional check-ups, bowel habits, sleep, urination concerns, caffeine intake, sexual functioning and safe sex practices) (a copy of the Thai Health Improvement Profile is available from the corresponding author upon request). The Thai Health Improvement Profile findings were used to draw patients' (and health professionals') attention to the indicators of each of the physical health risks by using a traffic light system (i.e., green flag = 'no action required'; and red flag = 'action required'). The recommended treatment approaches and target lifestyle behaviours that require improvement are identified by the types of red-flagged items and how they cluster together. For example, a patient may have red-flagged items for central obesity, BMI, hypertension and cholesterol levels in addition to poor diet; indicating and reinforcing to the patient that improving dietary intake would help to address the cluster of obesity-related concerns. The Thai Health Improvement Profile screening was completed at baseline, 3 months, 6 months, 9 months and 12 months with the participants in the treatment group, with each session lasting 20–45 min.

In line with previously reported procedures (Bressington et al., 2014, 2018; Meepring et al., 2018) the community psychiatric nurses discussed the Thai Health Improvement Profile findings with participants and their family members/carers and devised individualised physical health care plans. The community psychiatric nurses used motivational interviewing techniques with patients and family members throughout the assessments and follow-up meetings to discuss lifestyle and physical health problems/risks and enhance the patients' intrinsic motivation to adopt healthy lifestyle behaviours.

The motivational interviewing approaches were underpinned by the transtheoretical model of change (Prochaska, 2008). This model proposes that people move backwards and forwards across six stages of health behaviour change (precontemplation, contemplation, preparation, action, maintenance, and termination/relapse). Precontemplation is usually defined as a person not intending to act to change a health behaviour in the next 6 months. Contemplation is associated with an awareness of the need to change but is dominated by ambivalence that may last for long periods and maintain current unhealthy behaviours. Preparation is where people recognise the need to change, intend to act in the immediate future, often have a general plan and have usually already taken some steps towards making a change. The action stage is where individuals have made observable health behaviour changes within the past six months and the maintenance stage is where the change has been sustained for over 6 months and the individual's efforts are mainly directed at relapse prevention (Prochaska, 2008). Given the varying support, information requirements and motivational needs across the different stages of change, interventions to promote/maintain health behaviour change should be stage-specific and therefore tailored to match the patient's current stage of change. The patients' stage of change was assessed at every meeting as this can vary considerably across time (i.e. a person can move from maintenance to precontemplation in a short period of time).

In order to ascertain the participants' current stage of change, their readiness to change a healthy lifestyle behaviour, perception of importance of changing and confidence to change were rated (on a 1–10 scale, with 10 being 100 % ready/important/confident) in each session and these ratings were used to guide the focus/aims of therapeutic interventions (Petrocelli, 2002). The specific motivational interviewing approaches used at each session were determined based on the patients' current stage of change. For example, those participants deemed to be in the precontemplation phase of Prochaska's model (i.e. those with very low scores for *importance*) were engaged in conversations about the importance of health behaviour change (i.e. increasing physical activity) supported by evidence of the importance to change from the completed Thai Health Improvement Profile tool. Whereas, the therapeutic aim for those in the contemplation stage of the model (i.e. those with *importance* and *readiness* scores in the mid-range) was to guide them to build their own reasons for change, explore ambivalence about changing, and build their perceptions of readiness and importance to improve the target health behaviour. Participants that were at the action stage (for example, those already making a change, with high scores for *importance* but lower scores for *confidence*) were engaged in conversations about how to enhance their confidence to maintain the health behaviour change and were encouraged to monitor and celebrate progress made to date.

The individualised physical health care plans to manage bodyweight were constructed using the results of the Thai Health Improvement Profile assessment tool findings. The care plans' goals, objectives and actions were discussed and agreed with both patients and carers/family members. All mutual goals needed to be Specific, Measurable, Achievable, Realistic, and Time orientated (SMART). General recommendations for interventions were provided on the Thai Health Improvement Profile tool. For example, for a BMI or waist circumference value red flagged (at risk) the nurse is guided to provide "*advice and support on diet and exercise, consider referral to local weight/exercise management programme*" and if the patient also has a red flag for eating less than 5 portions of fruit and vegetables per day the recommendations include "*Offer recommendations on reduction of health risks with 5-a-day; Address potential barriers to accessing and eating fruit/vegetables; Agree and implement a plan with the patient (and carer/family member if appropriate); Include referral to other*

members of the clinical team e.g. occupational therapist for meal planning, shopping and cooking skills". In the above example, the care plan's specific goals, objectives and actions would be individualised based on the patient's current health behaviours/dietary habits and their collaboratively identified goals (i.e. replacing a fried snack usually eaten every morning with two slices of mango prepared by the patient's parent). Similarly, if an overweight patient was physically inactive the Thai Health Improvement Profile tool suggests recommending *30 min of activity 5 days a week*. The nurse would ascertain the current level of activity, available resources, patient preferences for activities, potential barriers and home circumstances before suggesting and agreeing on SMART exercise goals (i.e. accompany parent to walk to the rice fields to check the fish traps at 7 am on Monday, Wednesday and Friday mornings).

The community psychiatric nurses evaluated progress throughout the one-year intervention by referring to the previously completed Thai Health Improvement Profile tools, associated care plans and re-ratings of importance, confidence and readiness during their monthly follow-up meetings with patients and their accompanying family member/carer. Once objectives identified in the care plan were met, the nurse and patient/family member would select other red-flagged areas of health behaviours related to bodyweight to include in a new care plan. The community psychiatric nurses' fidelity to the treatment model was assessed during training but was not objectively evaluated during the trial. Community psychiatric nurses delivering the Thai Health Improvement Profile intervention were provided with ongoing support and supervision from the first author (SM).

2.9. Intervention training

Five participating community psychiatric nurses were provided with a one-day (8 hour) training workshop (delivered by SM and DB) and an intervention manual, which outlines each Thai Health Improvement Profile health-check item. The training covered using the Health Improvement Profile tool, the recommended interventions for each red-flagged Thai Health Improvement Profile item, strategies in engaging patients to make effective changes in health-related behaviours in accordance with the transtheoretical model of change, the motivational interviewing approach, formulation of individualised care plans, and follow-up actions. The theoretical aspects of the training and review of the Thai Health Improvement Profile tool/handbook were delivered over 3 h. In the afternoon the nurses spent 1.5 h rehearsing using the Thai Health Improvement Profile tool to conduct a comprehensive assessment and an hour practising how to make collaborative care plans. The community psychiatric nurses were assessed for their competence in using the Thai Health Improvement Profile intervention via performance ratings using case studies and supervised role-play during the final section of the training.

2.10. Treatment-as-usual

The control group (and the Thai Health Improvement Profile intervention group) received their usual mental/physical health care and attended outpatient appointments/treatments as indicated by their health needs determined by the treating psychiatrist and other healthcare team members. Routine psychosocial treatment at the outpatient clinic consisted of brief non-specific counselling and assessment of patients' psychiatric symptoms, social functioning, adverse treatment effects, risk to self/others and drug/alcohol use. As all participants were prescribed antipsychotic medication, their usual treatment for physical health was determined by the clinical setting's policy for monitoring physical health in people prescribed antipsychotics. This involved three-monthly monitoring of cardiometabolic health, including measurements of body weight, height, waist circumference and vital signs. None of the included treatment-as-usual participants received any other physical health monitoring or intervention programme beyond usual care (as per the study exclusion criteria).

2.11. Outcome measures

2.11.1. Primary outcome

Participants' body weight was measured using regularly calibrated scales at baseline and at 3, 6, 9 and 12 months after the start of the intervention by outpatient department staff who were blind to group allocation. Clinically meaningful weight gain was classified as at least 7 % of baseline body weight. Although there is no universally agreed definition of clinically significant weight gain and some studies use a ≥5 % increase in body weight, we adopted the commonly used definition of 7 % (Campforts et al., 2023) as this increase has a potentially detrimental impact on health and this definition was used in the other weight gain prevention studies in people with early psychosis (i.e. Álvarez-Jiménez et al., 2010; Curtis et al., 2016; O'Donoghue et al., 2022). Additionally, by using a ≥7 % criterion direct comparisons with other physical health interventions in this population are possible.

2.12. Secondary outcomes

2.12.1. Indicators of obesity

Waist circumference and BMI were measured and calculated at the same time participants were weighed.

2.12.2. Health-related quality of life

Health related quality of life was self-rated using the Thai language version of the brief World Health Organization Quality of Life measure (WHOQOL-BREF; Whoqol Group, 1998). The Thai WHOQOL-BREF is a reliable and valid self-reported measure of health-related quality of life with acceptable psychometric properties in clinical and non-clinical populations (Li et al., 2009; Jiratchayaporn et al., 2020; Sirisuwan et al., 2022) and is used widely by the Royal Thai Government's Ministry of Public Health (Chantarasap et al., 2019). The Thai WHOQOL-BREF contains 26 questions. Each question is scored on a 5-point Likert scale (i.e. from "1 very poor", to "5 very good"; or "1 not at all", to "5 an extreme amount"). Higher scores indicate better quality of life. There are four subscales (physical health, psychological health, social relationships and environment) and two separate facets (overall quality of life and general health). The WHOQOL-BREF domain scores were converted to WHO 0–100 scores in accordance with WHO guidelines (WHO Division of Mental Health, 1996).

2.12.3. Satisfaction with physical health care

The Thai version of the Client Satisfaction Questionnaire (CSQ8) was used to assess participants' satisfaction with physical health care at baseline and 12 months after the interventions started. The CSQ8 Thai language version was translated into Thai and validated for use with people receiving psychiatric care in 2000 (Kongsakon and Jareonsettasin, 2000) demonstrating acceptable internal consistency (Cronbach's alpha coefficient for all scales of >0.70) and test–retest reliability (Pearson's correlation of 0.697). The scale has eight items rated on a four-point scale, with a higher score indicating a higher level of overall satisfaction with physical health care.

2.13. Covariates

The Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) was used to measure the baseline level of depression among the participants as a co-variant of study outcomes. This is because some studies have shown that symptoms of depression are associated with an increased risk of developing obesity (Blaine, 2008). The Thai version of the HADS (Nilchaikovit et al., 1996) is widely used and is reported to have satisfactory psychometric properties as a screening instrument to assess anxious and depressive states in a range of Thai clinical populations (Phabphal et al., 2007; Kongkasuwan et al., 2016).

2.14. Data analysis strategy

Data were analysed using SPSS (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp).

Descriptive statistics were used to summarise the socio-demographic and clinical characteristics and levels/scores of primary and secondary outcomes of the two study groups at baseline. Differences in baseline demographic and clinical characteristics between the Thai Health Improvement Profile and treatment-as-usual groups were evaluated using the independent samples *t*-test or Chi-square/Fisher's exact test depending on the variable type and cell counts. The Little's Missing Completely at Random (MCAR) test was used to assess whether missing data (weight, BMI, waist circumference and quality of life) occurred randomly in the data set or exhibited a systematic pattern. The chi-square value of 14.55 with DF = 29 and p = 0.988 suggested that the missing data were missing completely at random.

Outcome analyses were carried out on an intention-to-treat basis by replacing any missing data using the multiple imputation method (with 20 imputations and an automatic imputation method selection). The primary outcome at the 3 month follow-up was compared between the two groups using the proportion test (as there were no missing data). The primary outcome at the 12 month follow-up was analysed using pooled univariate logistic regression (the dependent variable was ≥7 % gain in body weight — yes/no, and the independent variable was group). Whereas, a generalised estimating equation (GEE), which can account for data missing completely at random, was used to evaluate the parameters for group and time effects, and also group-by-time interaction on the secondary outcome measures (reduction of BMI and waist circumference, quality of life and satisfaction with physical health care) over the duration of the study. The interaction between group and time shows whether changes over time differ in the two groups. We report sample means and standard deviations of outcome variables and the type III overall effects (group, time, and group-by-time). An independent working correlation matrix was used in GEE models after comparing the quasi-likelihood under the independence model information criterion (QIC) and the corrected quasi-likelihood under the independence model information criterion (QICC). Covariates such as those clinical and demographic characteristics showing significant differences between groups at baseline, and level of depression were added to the GEE models. The level of significance for statistical tests was set at $p < 0.05$ (2-tailed).

3. Results

Fig. 1 is the trial CONSORT diagram showing participant flow through the study.

Overall, 145 patients were identified from the medical records for initial study eligibility screening. A total of 33 were excluded as they did not meet the inclusion criteria (23 were diagnosed with psychosis for > 5 years; five were involved in another physical health intervention beyond usual care; and five were deemed too unwell to have the capacity to provide informed consent).

Six of the 112 eligible potential participants declined to take part after being approached by research team members, resulting in an overall response rate for eligible participants of 93 %. Finally, 106 proceeded to be randomised to either the Thai Health Improvement Profile intervention or treatment-as-usual (see Fig. 1 for the study flow diagram). All 106 randomised participants completed the 3-month follow-up assessments, but 46 were lost at the 12 month follow-up point for the primary outcome measure (43 % attrition; 23 in each group).

At the 12-month follow-up one participant in the treatment-as-usual group did not attend the primary outcome measure assessment but completed the secondary outcome measures and one of the Thai Health Improvement Profile group participants did not complete the secondary outcome measures despite attending the assessment for the primary outcome. In summary, seventeen participants dropped out of the study due to non-COVID related reasons. Some of these reasons were closely related to traditional Thai culture, such as being ordained as a Monk or seeking traditional Thai alternative treatments/medicines. Participant attrition was often due to the COVID-19 pandemic which struck Thailand at the midpoint of the trial (i.e. after the 3-month follow-ups had been completed). Due to COVID-19 the Thai government mandated restrictions on patient movements that necessitated some participants attending alternative outpatient clinics in general hospitals closer to their homes. The pandemic also created job losses and economic hardship for some participants and their families, resulting in migration to find work. Several participants also moved back to their rural home provinces where they perceived they were safer from the virus and would be able to provide support for family members. The specific reasons for attrition in the Thai Health Improvement Profile and treatment-as-usual groups are detailed in Supplementary Table S1.

3.1. Harms/adverse effects

During the trial, five participants were admitted to hospital (three after being in vehicle accidents and two that received court directed treatment orders to attend substance abuse rehabilitation centres). These events were not considered to be a direct result of the trial after discussion with local clinicians advising the research team. No other adverse events or safety concerns were reported.

3.2. Demographic and clinical characteristics

Full details of the participants' baseline demographic and clinical characteristics are shown in Table 1. In summary, participants had an average age of 36 years, around half were female and most were not in regular paid employment. Only one in five had completed a qualification beyond secondary school and less than a third were married. Almost three quarters paid for their mental health treatment via welfare benefits. On average participants reported a duration of illness of just under 2 years and the majority had a diagnosis of either *schizophrenia* or *other non-organic psychotic disorders*. Most (69 %) were prescribed an atypical antipsychotic, with just over one in ten prescribed clozapine. Few participants were prescribed medication for diabetes, hypertension or dyslipidaemia. None of the participants received any pharmacological weight loss treatments prior to or during the study. Analysis of the baseline characteristics revealed statistically significant differences between the Thai Health Improvement Profile and treatment-as-usual groups in relation to employment status, weight, BMI and waist circumference measurement. These characteristics served as covariates in subsequent analyses.

3.3. Primary outcome

3.3.1. Proportion that gained ≥7 % body weight

At the three month follow-up, three participants (5.66 %) in the Thai Health Improvement Profile group (n = 53) and four (7.55 %) in the treatment-as-usual group (n = 53) had gained ≥7 % of baseline body weight (no missing cases). The proportion test showed there was no statistically significant difference between these two proportions ($p > 0.05$). After replacing missing values using multiple imputation (23 missing in each group) at the one-year follow-up the pooled number of participants that gained ≥7 % of baseline body weight in the treatment-as-usual group was 28.4 (53.58 %) and 8.3 (15.66 %) in the Health Improvement Profile group. Pooled univariate logistic regression showed that the treatment-as-usual group has higher odds than the Health Improvement Profile group of gaining ≥7 % of baseline body weight (OR = 6.52; 95 % CI: 1.88–2.65, p = 0.004).

3.4. Secondary outcomes

3.4.1. Obesity — waist circumference measurement and BMI

Waist circumference and BMI descriptive data are summarised in Table 2.

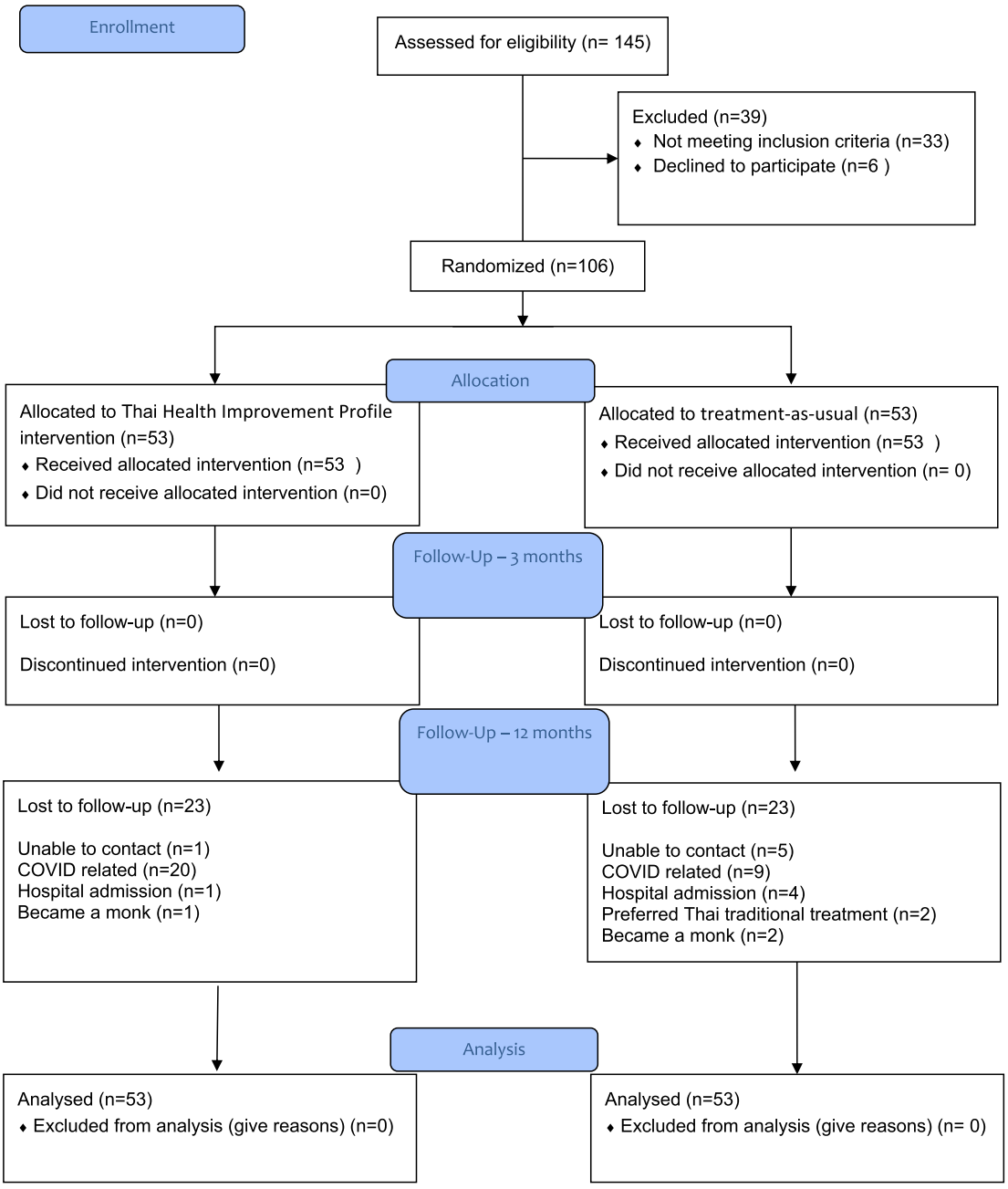

Fig. 1. Study flow diagram.

3.4.1.1. Waist circumference. After taking into consideration the background information (age, gender, duration of illness, on second generation antipsychotics yes/no, depression scores (HADS)), we found in the waist circumference GEE model, only group ($p = 0.003$), interaction term group * time ($p < 0.001$), education level ($p = 0.012$) and gender ($p = 0.009$) were significant. The effect size of the Thai Health Improvement Profile group on waist circumference Cohen's f^2 is 0.13 (Selya et al., 2012), which is a small to medium effect when adjusting for education level, gender and time (Table 3).

3.4.1.2. Body Mass Index. Within the BMI GEE model, group ($p = 0.011$), time ($p = 0.011$), interaction term group * time ($p = 0.003$), education level ($p = 0.007$) and HADS depression score ($p = 0.013$) were all significant. The Cohen's f^2 effect size of the Thai Health Improvement Profile treatment group on BMI is 0.08, which is small to medium after adjusting for education level, time and HADS score. Please see Table 3 for the full results.

3.4.2. Heath related quality of life

Quality of life descriptive statistics are shown in Table 2. The GEE models showed that there were significant interaction term group * time effects (favouring the Thai Health Improvement Profile group) for three quality of life domains with small effect sizes (physical, $f^2 = 0.06$; psychological, $f^2 = 0.01$; environment, $f^2 = 0.02$) and the general health single item ($f^2 = 0.04$). No statistically significant effects were found in the social relationship domain or the overall quality of life single item. Table 4 provides full details of the results.

3.4.3. Satisfaction with physical health care

The group and interaction term were found to have no effect on the level of satisfaction with physical health care. Please see Table 2 for

Table 1
Baseline demographic/clinical characteristics of the participants and differences between groups.

Variable	All (n = 106)		HIP (n = 53)		TAU (n = 53)		t, X^2 or Fisher	p-Value
	Mean	SD	Mean	SD	Mean	SD		
Age in years	36.4	12.1	35.9	11.3	36.8	13.0	t = 0.42	0.678
Weight kg	68.4	16.7	74.1	17.2	62.8	14.1	t = −3.71	<0.001
BMI kg/m^2	25.2	5.4	27.0	5.8	23.4	4.3	t = −3.66	<0.001
Waist circumference cm	86.4	11.3	91.0	11.9	81.9	8.5	t = −4.51	<0.001
Duration of illness in months	23.4	13.9	22.2	13.0	24.7	15.0	t = 0.92	0.362

Variable		All (n = 106)		HIP (n = 53)		TAU (n = 53)		t, X^2 or Fisher	p-Value
		n	%	n	%	n	%		
Gender	Male	56	52.8	28	52.8	28	52.8	X^2 = 0.00	1.000
	Female	50	47.2	25	47.2	25	47.2		
Employment status	Unemployed	33	31.1	14	26.4	19	35.8	Fisher = 9.52	0.049
	Freelance	8	7.5	8	15.1	0	0.0		
	Housewife/husband	22	20.8	10	18.9	12	22.6		
	Employee	18	17.0	10	18.9	8	15.1		
	Other	25	23.6	11	20.8	14	26.4		
Educational level	None	5	4.7	1	1.9	4	7.5	Fisher = 6.47	0.167
	Primary	38	35.3	16	30.2	22	41.5		
	Secondary	50	47.2	28	52.8	22	41.5		
	University/college	10	9.4	5	9.4	5	9.4		
	Higher than bachelor's degree	3	2.8	3	5.7	0	0.0		
Marital status	Single	56	52.8	27	50.9	29	54.7	Fisher = 1.65	0.800
	Married	33	31.1	19	35.8	14	26.4		
	Divorced	11	10.4	4	7.5	7	13.2		
	Widowed	2	1.9	2	3.8	2	3.8		
	Others	2	1.9	1	1.9	1	1.9		
Financial support for treatment	Civil servant	13	12.3	5	9.4	8	15.1	X^2 = 1.75	0.626
	National Welfare Scheme for subsidised treatment	68	64.2	33	62.3	35	66.0		
	Social security scheme	10	9.4	6	11.3	4	7.5		
	Other/private insurance	15	14.2	9	17.0	6	11.3		
Psychiatric diagnosis	Schizophrenia	34	32.1	17	32.1	17	32.1	Fisher = 4.49	0.344
	Acute and transient psychotic disorder	10	9.4	6	11.3	4	7.5		
	Schizoaffective disorders	7	6.6	1	1.9	6	11.3		
	Unspecified non-organic psychosis	5	4.7	2	3.8	3	5.7		
	Other non-organic psychotic disorders	50	47.2	27	50.9	23	43.4		
Prescribed atypical antipsychotics	Yes	73	68.9	39	73.6	34	64.2	X^2 = 1.10	0.294
	No	33	31.1	14	26.4	19	35.8		
Prescribed clozapine	Yes	13	12.3	4	7.5	9	17.0	X^2 = 2.19	0.139
	No	93	87.7	49	92.5	44	83.0		
Prescribed medications for diabetes	Yes	1	0.9	0	0.0	1	1.9	Fisher = 1.01	1.000
	No	105	99.1	53	100	52	98.1		
Prescribed medications for hypertension	Yes	7	6.6	5	9.4	2	3.8	Fisher = 1.38	0.437
	No	99	93.4	48	90.6	51	96.2		
Prescribed medications for dyslipidaemia	Yes	1	0.9	0	0.0	1	1.9	Fisher = 1.01	1.000
	No	105	99.1	53	100	52	98.1		

Note: Employment status "other" = i.e. casual employment or working for friends/family; HIP = Thai Health Improvement intervention; TAU = treatment as usual.

satisfaction with physical healthcare (total CSQ8 score) descriptive statistics and Table 4 for full results.

4. Discussion

The primary objective of this trial was to establish the efficacy of the Thai Health Improvement Profile intervention when compared with treatment-as-usual for the prevention of clinically significant weight gain (≥7 % body weight) in people with early stage psychosis over one year. There were no statistically significant differences in the proportion of participants that gained ≥7 % body weight at 3 months, but statistically significant differences were found at 12 months, with treatment-as-usual participants having a 550 % increase in the odds of experiencing clinically significant weight gain. The results also showed significant reductions in waist circumference measurement and BMI (secondary outcomes) favouring the Thai Health Improvement Profile group over the 12 month study duration, with small to medium effect sizes. However, it should be noted that multiple imputation was used to replace 43 % of missing data at 12 months. Although the multiple imputation is justified to reduce the waste of resources caused by missing data (Sterne et al., 2009) it is possible that imputing a large proportion of data may have distorted the results. For example, this may have resulted in an underestimate of the extent of weight gain and therefore an overestimate of the true effect of the intervention.

The positive results of the current study are encouraging, particularly as few studies have been designed to prevent clinically significant weight gain in people with early stage psychosis in the longer term, and these have reported mixed findings. For example, Curtis et al.'s (2016) trial of an individualised lifestyle and life skills intervention for participants with first episode psychosis reported significant differences in weight gain between groups, with 13 % of the intervention group and 75 % of the treatment-as-usual gaining ≥7 % weight at the three-month follow-up. Similarly, a trial of an early behavioural intervention (Álvarez-Jiménez et al., 2010) to manage antipsychotic induced weight gain in 62 people with first episode psychosis resulted in a significantly smaller proportion of participants in the intervention group gaining at least 7 % of body weight compared to the treatment-as-usual group directly after the three month intervention period (39 % vs 79 %) and at the 6 month follow-up (56 % vs 88 %). However, these improvements were not maintained at either the 12- or 24-month follow-up, with over three quarters

Table 2
Waist circumference, BMI, quality of life and satisfaction with physical healthcare in both groups at each measurement point.

Variable	Treatment-as-usual (n = 53)			Health Improvement Profile (n = 53)		
	Missing	Mean	SD	Missing	Mean	SD
BMI (kg/m²)						
Baseline	0	23.41	4.27	0	27.05	5.83
3 months	0	23.89	4.10	0	25.94	5.27
12 months	23	24.92	4.09	23	26.10	4.76
Waist circumference (cm)						
Baseline	0	81.91	8.48	0	90.97	11.94
3 months	0	83.75	8.74	0	88.02	8.08
12 months	23	87.80	7.54	23	88.30	10.45
Overall QOL single item						
Baseline	0	3.23	0.97	0	3.26	0.84
3 months	0	3.21	0.97	0	3.19	0.65
12 months	24	3.41	0.91	22	3.52	0.68
QOL general health single item						
Baseline	0	3.40	1.36	0	3.28	1.46
3 months	0	2.89	1.07	0	2.13	1.02
12 months	24	4.34	0.61	22	4.10	0.79
QOL physical domain						
Baseline	0	56.51	13.34	0	56.60	11.26
3 months	0	53.87	11.45	0	62.04	11.28
12 months	24	67.21	10.24	22	64.65	11.21
QOL psychological domain						
Baseline	0	56.15	13.18	0	56.79	13.44
3 months	0	52.38	10.38	0	58.40	12.64
12 months	24	63.62	13.50	22	64.23	13.12
QOL social domain						
Baseline	0	48.83	17.39	0	48.81	14.80
3 months	0	50.34	13.22	0	45.72	13.99
12 months	24	56.24	13.34	22	58.94	15.57
QOL environment domain						
Baseline	0	60.15	11.64	0	62.25	11.53
3 months	0	56.04	10.31	0	60.51	10.31
12 months	24	66.93	10.70	22	64.45	10.87
Satisfaction with physical healthcare score						
Baseline	0	25.40	3.28	0	26.18	2.97
12 months	24	19.66	0.97	22	19.45	1.59

Note: QOL = quality of life; SD = standard deviation.

Table 3
The results of GEE model to assess the effects of groups, time on waist circumference and Body Mass Index (kg/m²).

Parameter	Coefficient	95 % Wald confidence interval		p
		Lower	Upper	
Waist circumference				
Treatment allocation				0.003
[TAU]	Ref			<0.001
[HIP]	9.26	5.41	13.12	
Time				0.136
[Baseline]	Ref			
[3 months]	1.84	0.48	3.21	0.008
[12 months]	5.70	3.34	8.06	<0.001
Treatment allocation * time				<0.001
HIP * [3 months]	−4.80	−7.31	−2.29	<0.001
HIP * [12 months]	−8.33	−12.26	−4.41	<0.001
Gender				0.009
Male	Ref			
Female	4.42	−7.74	−1.10	0.009
Education				0.012
None	Ref			
Primary	5.10	0.20	10.00	0.041
Secondary	0.57	−3.88	5.02	0.802
College/uni and higher	5.47	0.09	10.85	0.046
Body Mass Index				
Treatment allocation				0.011
[TAU]	Ref			
[HIP]	3.39	1.48	5.31	0.001
Time				0.011
[Baseline]	Ref			
[3 months]	−0.31	−1.16	0.54	0.475
[12 months]	0.86	−0.41	2.12	0.183
Treatment allocation * time				0.003
HIP * [3 months]	−0.90	−1.85	0.05	0.065
HIP * [12 months]	−2.56	−4.19	−0.93	0.002
Education				0.007
None	Ref			
Primary	3.60	1.34	5.86	0.002
Secondary	1.47	−0.73	3.68	0.191
College/uni and higher	3.85	0.33	7.36	0.032
Depression score baseline	−0.21	−0.37	−0.04	0.013

Note: HIP = Thai Health Improvement Profile Intervention; TAU = treatment-as-usual.

of both groups having gained ≥7 % weight over the longer term (Álvarez-Jiménez et al., 2010). Whereas, a recent trial of integrating a physical health nurse in the care of 77 young people with first-episode psychosis reported a non-statistically significant difference of 41 % in the intervention group and 44 % of the treatment-as-usual group gaining ≥7 % weight over six months (O'Donoghue et al., 2022).

The current trial included participants with an average duration of illness around 2 years, therefore it is not appropriate to make direct comparisons with earlier studies that included people with first episode psychosis newly prescribed antipsychotics (due to the potential for rapid weight gain in the first few months of treatment; Manu et al., 2015). However, the findings from the current study show that is possible to obtain similar, or perhaps better, weight management results in people that have experienced psychosis beyond the first episode. There may be several reasons for our positive results. Although it would seem logical to prevent weight as early as possible, it is plausible that at the start of treatment patients have less capacity to make lifestyle changes due to an initial focus on controlling psychotic symptoms. Perhaps more importantly, the experimental interventions used in the earlier studies were delivered over a maximum of 6 months, whereas the Thai Health Improvement Profile was integrated into regular treatment over one-year. It is therefore conceivable that effective weight management interventions need to be delivered over the long-term by clinicians that routinely work in the health service to realise and maintain benefits over time. A longer term follow-up is needed to further assess whether the effects of the Thai Health Improvement Profile and its impacts on health lifestyle changes are sustained after the one-year intervention period.

It is possible that family involvement may partially account for the current study's comparatively positive results as none of the earlier studies involved participants' family members or carers in the interventions, whereas a family member of all participants attended appointments and participated in the Thai Health Improvement Profile intervention. The involvement of families and carers in weight management and other physical health improvement studies may be particularly important given that informal carers should be core partners in the delivery of care for people with mental health illness (Australian Government Department of Health, 2017; Hannan, 2013). A recent systematic review demonstrated how informal carers often play a key role in monitoring the physical health of their relatives, navigating physical health care systems and encouraging the adoption of a healthy lifestyle (Ho et al., 2021). A systematic review and meta-analysis of 65 RCTs of peer-supported lifestyle interventions on body weight reduction in the general population (Lim et al., 2021) also demonstrated significantly reduced weight, BMI, and waist circumference. We also hypothesise that the use of the Transtheoretical Model of Change (Prochaska, 2008) to underpin and guide stage specific motivational interviewing interventions in combination with objective evidence of the importance for the need to change from the Thai Health Improvement Profile tool may have

Table 4
GEE models for health-related quality of life and satisfaction with physical health care.

	Coefficient	Std. error	95 % CI lower	95 % CI upper	p
Physical health domain					
(Intercept)	60.21	1.74	56.80	63.62	<0.001
Treatment allocation					0.011
[TAU]	Ref				
[HIP]	−7.76	2.17	−12.01	−3.51	0.886
Gender					<0.001
[Male]	Ref				
[Female]	6.49	1.40	3.74	9.24	<0.001
Time					
[Baseline]	Ref				
[12 months]	−2.64	2.55	−7.63	2.35	0.300
Depression score baseline	−0.32	0.13	−0.59	−0.05	0.018
[HIP] * [12 months]	8.08	3.26	1.68	14.47	0.013
Psychological health domain					
(Intercept)	58.83	2.06	54.78	62.85	<0.001
Treatment allocation				0.07	
[TAU]	Ref				
[HIP]	2.85	1.59	−0.27	5.98	0.073
Gender					0.020
[Male]	Ref				
[Female]	−3.52	1.53	−6.54	−0.56	0.020
Time					0.538
[Baseline]	Ref				
[12 months]	−1.09	1.76	−4.54	2.37	0.538
Depression score baseline	−0.37	0.17	−0.71	−0.04	0.030
Social relationship domain					
(Intercept)	54.40	1.92	50.63	58.17	<0.001
Education					0.037
[None]	Ref				
[Primary]	−6.45	2.65	−11.67	−1.24	0.015
[Secondary]	−5.80	2.35	−10.41	−1.19	0.014
[College/uni and higher]	−7.55	3.41	−14.38	−0.73	0.030
Environmental health domain					
(Intercept)	64.27	1.56	61.21	67.32	<0.001
Treatment allocation				0.05	
[TAU]	Ref				
[HIP]	2.63	1.32	0.04	5.22	0.047
Gender					0.014
[Male]	Ref				
[Female]	−3.21	1.31	−5.76	−0.65	0.014
Time					0.059
[Baseline]	Ref				
[12 months]	−2.93	1.55	−5.96	0.11	0.059
Depression score baseline	−0.51	0.14	−0.78	−0.23	<0.001
Overall quality of life single item					
(Intercept)	2.89	0.389	2.13	3.65	<0.001
Education					0.006
[None]	Ref				
[Primary]	0.34	0.40	−0.45	1.12	0.405
[Secondary]	0.69	0.39	−0.10	1.47	0.086
[College/uni and higher]	0.31	0.41	−0.50	1.12	0.448
Depression score baseline	−0.03	0.01	−0.05	−0.01	0.013
General health single item					
(Intercept)	4.04	0.55	2.96	5.11	<0.001
Treatment allocation				0.02	
[TAU]	Ref				
[HIP]	−0.09	0.28	−0.62	0.45	0.751
Education					0.054
[None]	Ref				
[Primary]	−0.69	0.55	−1.76	0.39	0.209
[Secondary]	−0.79	0.55	−1.88	0.29	0.152
[College/uni and higher]	−0.26	0.57	−1.37	0.85	0.644
Time					<0.001
[Baseline]	Ref				
[12 months]	−0.51	0.25	−0.99	−0.03	0.039
[HIP] * [12 months]	−0.64	0.33	−1.28	−0.01	0.050
Satisfaction with physical health care					
(Intercept)	25.40	0.44	24.52	26.27	<0.001
Treatment allocation				0.38	
[TAU]	Ref				
[HIP]	0.78	0.60	−0.40	1.96	0.194
Time					<0.001
[Baseline]	Ref				
[12 months]	−5.74	0.48	−6.67	−4.81	<0.001
[HIP] * [12 months]	−0.99	0.71	−2.34	0.41	0.166

Note: HIP = Thai Health Improvement Profile Intervention; TAU = treatment-as-usual.

contributed towards our encouraging results. It is possible that nurses delivering the intervention may have been able to easily identify what is required to build motivation to change health behaviours and patients/family members may have appreciated the direct personal relevance of the individualised care plans. The findings from repeated assessments using the Thai Health Improvement Profile tool may also have provided objective evidence of improvements in the number of at-risk areas over time, effectively rewarding and reinforcing behavioural change.

The Thai cultural context may also particularly suit family-inclusive approaches towards improving the physical health of people with early stage psychosis. Many Thai family members normally live with or nearby their extended family (Napa et al., 2017). Providing care and support to family members with an illness is considered as a family responsibility (Stajduhar et al., 2013) and this responsibility is often shared among other relatives (Chompikul et al., 2009). Moreover, in Thai culture, older people hold power regarding decision-making (Napa et al., 2017) and younger family members often accept their suggestions (Tangchonlatip et al., 2010), which may be useful to motivate and maintain health behaviour change. Despite their potential, currently, there is a dearth of physical health improvement intervention studies for people with severe mental illness that involve family members/informal carers, and given the findings of the current study this should be considered by researchers as a potentially important area for future development.

The secondary trial outcomes unrelated to weight/obesity were health related quality of life and satisfaction with physical health care. These results should be treated with caution because the study was not powered to detect significant differences in these outcomes and the findings may therefore be artefacts of insufficient statistical power. Despite this, the GEE analyses demonstrated that when compared to treatment-as-usual the participants in the Thai Health Improvement Profile group experienced statistically significant improvements in three quality of life domains with small effect sizes. No statistically significant effects were found in the social relationship domain or the QOL general health single item. Similarly, there were no statistically significant differences between groups in relation to changes in satisfaction with physical health care. The relationship between reductions in obesity and improvements in quality of life has been widely demonstrated in the general population, particularly in relation to physical functioning and self-esteem (Kolotkin et al., 2001; Ross et al., 2009). Relatively few trials of combined interventions specifically designed to manage bodyweight in people with severe mental illness have reported corresponding statistically significant improvements in quality of life over the longer-term. One example is Chen et al.'s (2009) uncontrolled trial of a 10-week multi-modal weight management programme with 33 overweight patients diagnosed with schizophrenia that resulted in significant reductions in weight at the 48 week follow-up and corresponding improvements in three aspects of quality of life (bodily pain, general health and role emotional) as measured by the 36-Item Short Form Survey (SF-36; Ware Jr and Sherbourne, 1992) immediately post-intervention, however, quality of life outcomes were not reported at 48 weeks. Whereas, the Chinese Health Improvement Profile feasibility trial (Bressington et al., 2018) reported a positive trend in improvements in the Physical Component Subscale of the Short Form 12 Item (version 2) Health Survey (SF-12v2; Ware Jr et al., 1996), but this did not reach statistical significance ($p = 0.138$).

In terms of future research directions, subsequent studies of the Thai Health Improvement Profile should involve patients' family members, be conducted over at least one year and evaluate the intervention over multiple sites in order to establish the generalisability of findings. Future trials could also consider comparing the intervention with an active comparator, such as health monitoring and advice that does not incorporate the motivational interviewing component of the Thai Health Improvement Profile. This would enable researchers to blind participants to which intervention was intended to be superior and the group comparisons would provide an indication about which intervention components are most efficacious. Further studies would also benefit from including a study process analysis component to obtain information that could be used to further develop the intervention and should consider capturing data on participants' duration of exposure to antipsychotics. Antipsychotic exposure is important given that the early stage for initiating antipsychotic medication is a critical time for weight gain, and although this information may be inferred from duration of illness data it is quite possible that there are delays between diagnosis of psychosis and prescription of antipsychotics.

In relation to clinical practice, the study findings highlight that both Thai community mental health nurses and Thai people with early stage psychosis will engage well with the Thai Health Improvement Profile intervention and health checks. Community mental health nurses should therefore consider utilising a comprehensive physical health check tool with this patient population, incorporate stage-specific motivational interviewing approaches when constructing a collaborative physical health plan and consider involving a family member or primary carer when aiming to improve the physical health of people diagnosed with early stage psychosis.

4.1. Study limitations

Several limitations in relation to internal and external validity should be considered when interpreting the current study's findings. Given the nature of the Thai Health Improvement Profile intervention, despite blinding the primary outcome assessors it was not possible to blind the patient participants (or nurses delivering the intervention) to group allocation, which may have resulted in performance bias. Although the nurses' competence and fidelity to the treatment model were assessed during intervention training and they were provided with ongoing intervention supervision, we did not establish that they maintained fidelity to the treatment protocol when delivering the intervention as part of the trial. Due to this, we cannot be certain that the intervention was provided as originally intended. We also cannot be certain that there was no contamination of intervention effects between the experimental and control groups despite asking all participants not to discuss their experiences of the trial and the trial interventions with other participants. A further potential limitation is that although the transtheoretical model of change was used to guide the behaviour change aspects of the intervention, no overarching theoretical framework was used to develop the study, and this may impact upon the replicability of the study findings.

The use of randomisation strengthened the internal validity of the study; however, the randomisation did not produce comparable groups as there were some statistically significant differences between groups at baseline. Given the Thai Health Improvement Profile group had a higher mean body weight than the treatment-as-usual group at baseline this may have created a ceiling effect for further increases over the duration of the study, hence inflating the effect of the intervention. A further limitation was that no process analysis was conducted, hence participants did not provide any feedback on the intervention and we, therefore, cannot be sure which aspects or therapeutic ingredients of the intervention were most effective (i.e. the Health Improvement Profile tool, the motivational interviewing or the involvement of family members). Finally, there was over 40 % of participant attrition in both study groups for the primary outcome, which necessitated the replacement of missing data using multiple imputation in order to conduct intention-to-treat analyses, which may have resulted in distorting the resulting effect sizes.

5. Conclusion

The Thai Health Improvement Profile intervention was safe and more effective than treatment-as-usual in preventing clinically significant weight gain in Thai people with early stage psychosis over 12 months. Given the limitations of the current study there is inadequate evidence for recommending integration of the Thai Health Improvement Profile intervention into routine clinical practice at this stage. However, the results indicate that a large definitive randomised controlled trial of the Thai Health Improvement Profile is now warranted and future multi-site studies with longer follow-up should also be considered. The findings also highlight that Thai community mental health nurses should consider utilising a comprehensive physical health check tool, incorporate stage-specific motivational interviewing approaches and consider involving a family member when aiming to improve the physical health of people diagnosed with early stage psychosis.

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CRediT authorship contribution statement

Soontareeporn Meepring: Writing – review & editing, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Richard Gray:** Writing – review & editing, Writing – original draft, Methodology, Funding acquisition, Conceptualization. **Xia Li:** Writing – review & editing, Writing – original draft, Formal analysis. **Wai Tong Chien:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Yan Li:** Writing – review & editing, Methodology, Formal analysis. **Grace W.K. Ho:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Preeyakamon Kritkitrat:** Writing – review & editing, Writing – original draft, Methodology. **Daniel Bressington:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization.

Data availability

The raw patient-level data supporting the conclusions of this article will be made available by the authors upon request.

Declaration of Competing Interest

RG wrote the Health Improvement Profile and co-wrote the manual. He receives royalties from sales of the HIP manual. All other authors have no conflicts of interest.

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